ENDOGRAFT DEVICES AND METHODS TO USE THE SAME

PRIORITY

The present application is related to, claims the priority benefit of, and is a U.S. continuation patent application of, U.S. patent application Ser. No. 12/701,340, filed on Feb. 5, 2010 and issued as U.S. Pat. No. 9,050,091 on Jun. 9, 2015, which is related to, claims the priority benefit of, and is a U.S. continuation-in-part patent application of, U.S. patent application Ser. No. 11/997,147, filed Jun. 30, 2008 and issued as U.S. Pat. No. 8,398,703 on Mar. 19, 2013, which is related to, claims the priority benefit of, and is a U.S. national stage entry of, International Patent Application Serial No. PCT/US2006/029424, filed Jul. 28, 2006, which is related to, and claims the priority benefit of, U.S. Provisional Patent Application Ser. No. 60/703,421, filed Jul. 29, 2005. The contents of each of these applications and patents are hereby incorporated by reference in their entirety into this disclosure.

BACKGROUND

The present disclosure relates generally to tissue support, including devices and methods for aortic tissue support and for the treatment of aneurysms.

Aortic aneurysms are formed in a vessel when the wall of the vessel weakens, either due to disease, aging, heredity or some other process. The pressure of the blood flowing through the weakened area causes the vessel wall to balloon out, forming a blood-filled aneurysm sack. Although most aneurysms begin small, they tend to enlarge over time and the risk of the sack rupturing increases as the aneurysms grows larger. Acute rupture of the aortic aneurysm is a life-threatening event, due to massive internal bleeding with a mortality rate of 75-80%. According to the Society of Vascular Surgeons, ruptured aneurysms account for more than 15,000 deaths in the U.S. each year, making the abdominal aortic aneurysm (AAA) the 13th leading cause of death in the USA. Clearly, early detection and rupture prevention is the key to the final outcome in abdominal aortic aneurysm patient. However, the condition is under-diagnosed because most patients with AAA are asymptomatic. Consequently, the majority of the anomalies are discovered unexpectedly during routine tests or procedures. An estimated 1.7 million Americans have AAA, but only about 250,000-300,000 patients are diagnosed every year.

There is no proven medical treatment for AAA, and surgical repair has been the only common therapeutic option. A standard open repair has been associated with significant morbidity and mortality, prolonged recovery, and late complications. Because of these limitations, many patients and their physicians choose to defer operative treatment. Recently, endovascular aneurysm repair (EVAR) has become an alternative and some studies favorably compare endovascular repair with a standard open repair. However, significant concern exists relating to endovascular repair and its value is a subject of healthy debate. Endovascular abdominal aortic aneurysm repair has gained acceptance as a minimally invasive alternative to open surgery in selected patients. While long-term durability remains uncertain, patients and their physicians are willing to accept a degree of uncertainty in exchange for dramatic reduction in duration of hospital stay, and need for blood transfusion. Hence, improvements in the current EVAR devices can potentially make this approach standard for AAA repair.

Most patients diagnosed with AAA are not considered for surgery or endovascular repair unless the aneurysm is at least 5 cm in diameter, the point at which the risk of rupture clearly exceeds the risk of repair. Those with a smaller aneurysm are followed closely with regular imaging studies. There has been much speculation over the years about the preventive use of endovascular aneurysm repair in patients with aneurysms smaller than 5 cm, however, vascular surgeons so far have been reluctant to use EVAR for smaller aneurysms due to the concern about the long term durability of the technology and the lack of data demonstrating a clear benefit of early intervention. Moreover, although EVAR outcomes have improved over the years as physicians gain more experience with the procedure, it remains a technically demanding procedure that requires extensive training and this has limited the number of physicians qualified to perform EVAR.

Despite the shortcoming relating to training, a number of endovascular devices have been evaluated in clinical trials designed to gain approval from governmental agencies. These devices differ with respect to design features, including modularity, metallic composition and the structure of the stent, thickness, porosity, chemical composition of the polymeric fabric, methods for attaching the fabric to the stent, and presence or absence of an active method of fixing the device to the aortic wall with bars or hooks. With consideration of the numbers of structural variations between different brands of endovascular devices, it would be remarkable if clinical outcome were not equally dissimilar. Parameters such as frequency of endoleak, long-term change in size of the aneurysm sac, reason for device migration and limb thrombosis may be linked to specific device design features. Hence, any improvements in the deployment and attachment of stent graft would increase the utility of EVAR.

Important drivers and limiters of EVAR are playing a big role in the decision of the treatment. The drivers include: 1) Less invasive compared to open repair, which translates into shorter hospitalization and recovery and lower major morbidity; 2) Aging of the population will increase the incidence and prevalence of AAA and thoracic aortic aneurysm (TAA); 3) Increasingly informed patient population will generate strong patient demand for minimally invasive therapy, and 4) Next-generation devices, expected to address wider patient population (including those with thoracic disease) and reduce complications relative to current model. The limiters, on the other hand, include the following: 1) Clinical literature does not support prophylactic endovascular treatment of the small aneurysm with a low risk of fracture; 2) High rate of late complication necessitates extensive and potentially life-long post procedural follow-up (not required for open repair) and repeat intervention that makes endovascular therapy potentially more costly than open surgery; 3) Current device is not applicable to full-range of AMA patients; 4) Technical demands of the approach require devices and time-consuming training that may eliminate rapid adoption of new products, particularly for a specialist with a smaller case load, and 5) Surgical conversion is complicated by the presence of the stent graft. Improvements in the current devices would certainly make the drivers outweigh the limiters.

The most important trial conducted to date is the EVAR 1 study, which randomized over 1,000 elective patients with aneurysms 5.5 cm or larger comparing EVAR to open surgical repair. Thirty-day mortality published this year demonstrated a clear advantage of EVAR (1.6% vs. 4.7% for open repair). However, EVAR patients had significantly higher rates of secondary intervention (9.8% vs. 5.8%). A second version study, EVAR 2, is comparing EVAR with best medical treatment in patients unsuitable for surgical repair. The 12-month